

AMENDMENTS TO THE SPECIFICATION

Please replace paragraphs 0002, 0011, 0041, 0043, 0044, 0046, 0047, 0050, 0051, 0053, 0054, and 0057 with the following:

[0002] The invention relates to a dermal tissue transplantation system. More particularly, this invention relates to a system for obtaining, processing, collecting, and applying tissue samples for purposes of transplantation.

Please replace paragraph 0011 with the following:

[0011] The foregoing has outlined some of the more pertinent objects of the present invention. These objects should be construed to be merely illustrative of some of the more prominent features and applications of the invention. Many other beneficial results can be attained by applying the disclosed invention in a different manner or by modifying the invention as will be described. Accordingly, other objects and a fuller understanding of the invention may be had by referring to the following Detailed Description of the Invention, which includes the preferred embodiment.

[0041] As illustrated in Fig. 1, the dermal tissue nano-grafting system 10 of the present invention comprises three main components: a tissue particle harvester assembly 20 for cutting tissue particles from dermal tissue; a tissue particle collector 30 for receiving, separating and collecting the tissue particles; and a nanograft cell 40 in the form of a chambered dressing for receiving the collected tissue particles and culturing the growth of a dermal tissue graft. The ideal size of the tissue collected is about 50 – 300 microns; with the median particle size about 100 microns. The tissue particle harvester assembly 20 excises tissue particles of an appropriate size range from a dermal tissue source. The tissue particle collector 30 receives the harvested

tissue particle, collects and holds them in a proper environment to maintain their viability prior to seeding the particles in the nanograft cell 40. The nanograft cell 40 of the present invention is a type of tissue culture device for growing dermal graft tissue *in situ* on a skin graft site. Exemplary devices that may be used for the nanograft cell 40 are described in U.S. Patent 5,152,757, issued on October 6, 1992 to Eriksson, entitled "System For Diagnosis And Treatment Of Wounds" and U.S. Provisional patent application serial no. 10/361,341, entitled "Environmental Control Device For Tissue Treatment" filed on February 11, 2002, by Johnson, et al., the disclosures of which are incorporated by reference herein as though fully set forth.

[0043] A proper position of the cutting tool 90 relative to the dermal tissue source 14 relates to the depth of penetration of the cutting tool 90 into the layers of the dermal tissue 14. A proper positioning of the cutting tool 90 facilitates excising tissue particles of an appropriate size. The depth of penetration of the cutting tool 90 into the surface of the tissue 14 should range from about 0.01mm to about 0.9mm, and preferably should be about 0.1mm +/- 0.05mm, depending on the type of cutting tool 90 being used. The depth of penetration can be modified by any number of suitable means, including adjusting the proximity of the cutting tool to the tissue opening 54 in the housing 50, and by adjusting the cutting aspect 118 (see Fig. 5B) of the cutting features 114 of the cutting tool 90. The cutting aspect 118 of a cutting feature 114 is the reach of a cutting feature 114 beyond the cutting surface 94 of the tool 90. The harvester housing 50 can include a depth adjustment means for adjusting the proximity of the cutting tool to the tissue opening 54 in the housing 50. Such adjustment means will be known to and practicable in the present harvester assembly 20 by the ordinary skilled artisan. For example, as in Fig. 3, such adjustment means 58 can be made by moving an edge of the tissue opening 54

closer to, or farther away, from the cutting tool 90.

[0044] As exemplified in Figs. 5A and 5B, a tissue cutting tool 90 has a cutting surface 94 and cutting features 114 which project from the cutting surface 94 and impinges on the tissue source 14 to cut or excise tissue particles of an appropriate size from the tissue 14 when the cutting tool 90 is rotated. A rotatable shaft 96 extends from the tool 90 along its axis of rotation 100. The rotatable shaft 96 has a drive end 96a for engaging a drive means and a tool end 96b for mounting the cutting surface 94. The cutting tool shaft drive end 96a is receivable by a drive means 160 (e.g., see Figs. 10B and 18A & 18B) to impart rotation to the cutting tool 90. The rotating drum type cutting tool 90a shown in Figs. 5A and 5B has a tool end shaft 96b that extend from the tool 90 along the axis of rotation 100 opposite the drive end 96a. In Figs. 5A and 5B, the drum of the tool 90 has its axis disposed coaxially with the axis 100 of the rotatable shaft 96.

[0046] Not all tissue-cutting tools 90 practicable in the present harvester assembly 20 are rotary drum type cutting tools 90a. For example, rotating shaft cutting tools 90b (see Figs. 10 - 14) may be used. As exemplified in Fig. 10A, a rotating shaft cutting tool 90b comprises a rotatable shaft 120 having a drive end 122 for engaging the drive means 160 and a tool end 124 for mounting the tissue cutting surface 126 and cutting features 128. Figs 10A and 10B illustrate a rotating shaft-type tissue cutter tool 90b and harvester housing 130, and the rotating shaft-type tool 90b installed in a type of tissue harvester assembly 20b and connected to a drive means 160. The tool 90b has a side cutting bit feature 128 and is installable in a shear block type harvester housing 130. Other configurations of rotating shaft-type tissue cutter tools 90b are practicable in

the present harvester assembly 20b. Examples include: a fine scallop hypo-tube rotating shaft-type tissue cutter tool (Fig. 11); a course scallop hypo-tube rotating shaft-type tissue cutter tool (Fig. 12); a course scallop solid shaft-type tissue cutter tool (Fig.13); and alternative side cutting bit shaft-type tissue cutter tools (Fig. 14).

[0047] Other types of cutting tools 90 such as an end mill type cutting tool 90c (see Fig. 15) are also practicable in the present invention. The rotating drum and shaft tissue cutting tools 90a & 90b noted above can have both a drive end 96a and a tool end 96b. However, an end mill type cutting tool 90c will have only a shaft drive end 96a. A rotating end-mill cutting tool 90c comprises a rotatable shaft 132 having a drive end 96a for engaging the drive means 160 Fig. 10B and a tool end 96b for mounting a cutting drum 136. The cutting drum 136 is cylindrical and has an axis disposed coaxially with the drive and tool shaft ends 96a and 96b. The tool end 96b is attached at one end of the cutting drum 136 and the other end of the cutting drum 136 mounts a tissue cutting surface 138. The tissue-cutting surface can be constructed to have cutting features 114 similar to those practicable on the rotating drum type cutter 90a noted above. One of ordinary skill in the art is readily able to select from and adapt said cutting features 114 for incorporation onto the cutting surface 138 of a rotating end-mill cutting tool 90c of the present invention 10. The drum 136 has an outer circumferential surface that is closely receivable in a width of the interior space of the end mill housing 140 associated depth alignment means 142. The cutting drum 136 of the end mill tissue cutting tool 90c illustrated in Fig. 15 is a tapered cylinder proximate its tissue cutting surface 138. The benefit of this taper is that centrifugal force can facilitate the migration of excised tissue particles passing through the cutting surface 138 into the interior of the drum (shown in phantom) and up the interior walls

and away from the cutting surface 138. This will help to prevent clogging certain of the cutting features 114 with excised tissue particles.

[0050] As is illustrated in Figure 19, a port 170 may be provided within the cutter 90 to draw tissue that has been collected by the cutter 90 out of the housing 50. While the port 170 has been shown in the center of the cutter 90 along its axis of rotation in this embodiment, it is to be understood that multiple mechanisms for removing tissue from the housing are envisioned and described further herein. A housing mounting 166 is provided for stability and support to the user during operation of the harvester 20. Skid plates 164 are provided to ease in positioning of the cutter 90 at the tissue site, and to further aid in adjustment of the cutter 90 depth, especially when a shim stack 59, or other adjustment means known in the art, are provided external of the cutter 90.

[0051] Figures 20A, 20B, and 20C illustrate a tissue particle collector 30, which may be comprised of a port 170 positioned within or near the drive means of the cutter 90, and which may be accessible by a particle retriever 172, such as a syringe. The particle retriever 172 may then be used to inject or otherwise instill the tissue collected into a nanograft cell 40, as shown in Figure 1. Various mediums may be utilized to suspend the tissue within the tissue particle collector 30, and subsequently the nanograft cell 40. Such mediums may include, but are not necessarily limited to, saline.

[0052] Alternative embodiments of the tissue particle collector 30 (Fig. 2) for collecting tissue from the tissue particle harvester are illustrated in Figures 21-27. A separate flushing

container 180, as illustrated in Figure 21A, may be utilized to retrieve tissue from the cutter 90. The cutter 90 is removed from the harvester housing 50, and placed into the flushing container 180. A cap 182, or other cover, is screwed or otherwise secured to the container 180. A liquid medium, such as saline, is then flushed through a port 186 or luer, which may be integrated with the cap 182, or otherwise introduced into the container 180, and is directed towards the inner diameter and outer diameter of the cutter 90 by jets 184 or channels within the container 180.

[0053] An integral flushing container 190, as illustrated in Figure 21B, allows for collection of tissue without removal of the cutter 90 from its housing 50 (Fig. 2). In this embodiment, the cutter 90 has a solid filled core. A gasketed cap 192 is fitted over the integral flushing container 190, which may be the housing 50 having a receptor for the gasket cap 192, after tissue is cut from the donor site. The housing 50, with the cutter 90 in place, is removed from the tissue particle harvester 20 and fluid, which may be saline, is injected into the flushing container 190 through a luer fitting 194, or port. The flushing container 190 is manually agitated, by hand or by a mechanical agitator known in the art. After agitation, the tissue that has been cut by the cutter 90 is now suspended in the fluid which has been injected, at which point it may be drawn out of the integral flushing container 190 through the luer fitting 194 by means of a syringe or similar device known in the art.

[0054] An alternative embodiment of an integral flushing container 190 is illustrated in Figure 21C. A core filled cutter 90 is utilized to remove tissue from the donor site. A cap 196, which may be comprised of silicone or a material of similar physical characteristics is placed over the open-cutting face of the housing 50. The housing may include a luer for injecting fluid,

such as saline, which is then agitated by running the motor of the cutter 90. The agitation results in suspension of the tissue cut by the cutter 90 in the fluid, which may then be drawn out by through the luer 194 by a syringe or similar device, for insertion into a nanograft cell 40.

[0057] Still a further embodiment of the tissue particle collector 30 is the internal flushing channels 220 as illustrated in Figure 24. An internal core 222 is positioned within the cutter 90. The core 222, which remains stationary during rotation of the cutter 90, is toleranced tightly to the inner diameter of the cutter 90 while still allowing for free rotation of the cutter 90. Tissue enters channels 220 through openings 224 in the cutter during operation of the cutter 90. Fluid is flushed through the channels 220 during operation of the cutter into a collection chamber (not shown) for later removal to the wound site. It is to be understood that the fluid may also be flushed through the channels 220 when the cutter 90 is not being operated.

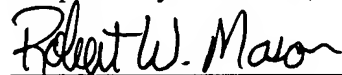
SUMMARY

If upon consideration of the above, the Examiner should feel that outstanding issues remain in the present application that could be resolved, the Examiner is invited to contact the undersigned at the telephone number indicated to discuss resolution of such issues.

No new matter has been added, these amendments are strictly to place the application in better condition for allowance due to clerical errors.

Applicant respectfully requests favorable consideration.

Respectfully submitted,

A handwritten signature in black ink, reading "Robert W. Mason", is written over a horizontal line.

Robert W. Mason

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